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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/380,546	11/29/99	WALLACH D	WALLACH=23

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EXAMINER	
WHITEMAN, B	

ART UNIT	PAPER NUMBER
1633	11

DATE MAILED: 05/16/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trad marks

Office Action Summary	Application No.	Applicant(s)	
	09/380,546	WALLACH ET AL.	
	Examiner	Art Unit	
	Brian Whiteman	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 November 1999* .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-43* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claims *1-43* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

15) ☐ Notice of References Cited (PTO-892)
16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
18) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
19) ☐ Notice of Informal Patent Application (PTO-152)
20) ☐ Other:

DETAILED ACTION

Applicant should amend the disclosure in its entirety by properly labeling each sequence with correct SEQ ID NO. Should applicant amend the claims, so that the claims no longer resemble the original claims, another restriction may be necessary.

During a telephone interview with Deborah Clark on May 9, 2001; the applicant made the observation that the restriction was made under 35 USC 121 and that the application has a USC 371 status; therefore, the restriction dated April 19, 2001 by examiner is withdrawn. A new restriction under 35 USC 371 is applied to this application.

Claims 1-43 are pending and under consideration in the instant application.

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1-10, 14, 16-18, drawn to DNA sequences encoding at least one isoform of a G1 protein; a vector comprising DNA sequence according to claim 1; transformed eukaryotic or prokaryotic host cells containing a vector according to claim 7; a method of producing at least one isoform of the G1 protein; a method of modulation of cell death or inflammatory processes comprising introducing into said cells a nucleotide sequence encoding one or more of proteins in the form of a suitable vector carrying said sequence; a method for the modulation of the FAS-R ligand or TNF effect on cells carrying FAS-R or p55-R comprising

introducing into said cells a nucleotide sequence encoding one or more of proteins in the form of a suitable vector carrying said sequence.

Group II, claims 11-13, 16-18, 20, 26, 28-29, and 32-36, drawn to an isoform of a G1 protein encoded by a DNA sequence according to claim 1, a pharmaceutical composition for the modulation of the FAS-R-ligand- or TNF- or other protein-effect on cells comprising, at least one isoform of a G1 protein; a fragment according to claim 11 being a peptide; a method for the modulation of cell death or inflammatory processes, comprising treating said cells with one or more G1 proteins according to claim 11; a method for the modulation of the FAS-R ligand or TNF effect on cells carrying a FAS-R or p55-R, comprising treating cells with one or more G1 proteins according to claim 11; a method for the modulation of cell death or inflammatory process, comprising treating cells with one or more inhibitors of one or more proteins/enzymes mediating said cell death or inflammatory process, said inhibitors being selected from the group consisting of: one or more G1 proteins according to claim 11; a method according to claim 16 wherein said protein is at least one of the G1 isoforms; a method for the modulation of the MORT-1-induced effect or MORT-1-binding protein-or-other protein-induced effect on cells comprising treating said cells in accordance with a method of claim 16; a method of modulating apoptopic processes or programmed cell death processes comprising treating said cells with one or more G1 proteins according to claim 11.

Group III, claim 15 and 21, drawn to antibodies specific for the G1 protein according to claim 11; a method for modulating the FAS-R ligand or TNF effect on cells carrying a FAS-R or a p55-R comprising treating cells with antibodies according to claim 15.

Group IV, claims 19, 24 and 30, drawn to a recombinant animal virus vector encoding a viral surface protein and a second sequence encoding a protein selected from the G1 protein according to one of claims 11-13; a method of treating tumor or HIV-infected cells or other diseased cells; a pharmaceutical composition comprising, as active ingredient, a recombinant animal virus vector encoding a protein capable of binding a cell surface receptor and encoding at least one isoform of a G1 protein according to claim 11.

Group V, claim 20, drawn to a method for the modulation of cell death or inflammatory process, comprising treating cells with one or more inhibitors mediating said cell death or inflammatory process said inhibitors being selected from the group consisting of: inhibitors of one or more G1 proteins according to claim 11.

Group VI, claims 22, 23 and 31, drawn to a method for modulating the FAS-R ligand or TNF effects on cells carrying a FAS-R or p55-R comprising treating cells with an oligonucleotide sequence encoding an antisense for at least part of the DNA sequence encoding a G1 protein according to claim 1; a pharmaceutical composition for modulating the FAS-R ligand or TNF or other protein effect on cells comprising an active ingredient, an oligonucleotide sequence encoding an anti-sense sequence of the G1 protein mRNA sequence according to claim 1.

Group VII, claim 25, drawn to a method for modulating the FAS-R ligand or TNF effect on cells comprising applying the ribozyme procedure in which a vector encoding a ribozyme sequence capable of interacting with a cellular mRNA sequence encoding a G1 protein according to claim 11.

Group VIII, claim 27, drawn to a method for isolating and identifying proteins, according to claim 11, comprising applying the two-yeast hybrid system.

Group IX, claim 37, drawn to a method for screening of a ligand capable of binding to a protein according to claim 11.

Group X, claim 38, drawn to a method for screening of a DNA sequence coding for a ligand capable of binding to a protein according to claim 11.

Group XI, claims 39-43, drawn to a method for identifying and producing a ligand capable of modulating the cellular activity modulated/mediated by MORT-1 or MORT-1 binding proteins; a method for identifying and producing a molecule capable of directly or indirectly modulating the cellular activity modulated/mediated by G1.

The inventions listed as Groups I-XI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT rule 13.2, they lack the same or corresponding special features for the following reasons:

37 CFR 1.475(c) states:

"If an application contains claims to more or less than one of the combination of categories of invention set forth in paragraph (b) of this section, unity of invention might not be present."

37 CFR 1.475(d) also states:

"If multiple products, processes of manufacture or uses are claimed, the first invention of the category first mentioned in the claims of the application and the first recited invention of each other categories related thereto will be considered as the main invention in the claims, see PCT Article 17(3)(a) and 1.476(c)."

37 CFR 1.475(e) further states:

"The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternative within a single claim."

In view of 37 CFR 1.475 (c), 37 CFR 1.475 (d), and 37 CFR 1.475 (e). Group I is considered the main invention to the product first mentioned in the claims, and the first recited invention drawn to other categories related thereto, e.g. a method of making, method of use.

Groups I, II, III, and IV are drawn to multiple distinct products that do not share the same inventive concept. The claimed invention of Groups I, II, III, and IV recite distinct materials that are neither require nor recited in the claimed invention of Group I, and thus have their own special technical features. For example, the proteins as claimed in Group II; the antibodies claimed in Group III and the recombinant animal virus vector in Group IV encompass structural materials that are distinct than the DNA sequences of Group I. Thus, it follows from the preceding analysis that the claimed inventions listed as Group I and Groups II-IV do not related to a single inventive concept under PCT Rule ~~13.1~~ because, under PCT Rule 13.2 they lack the same or corresponding special technical feature for the reasons set forth above.

In addition, the claimed inventions of Group I-XI recite distinct materials and/or methods steps that are neither required nor recited in the claimed invention of Group I, and thus lack the same or corresponding technical feature for the following reasons:

The special technical feature of Group I is considered to be a method for modulating a certain characteristic of a cell or a process by using DNA encoding a G1 protein.

The special technical feature of Group II is considered to be a method for modulating a certain characteristic of a cell or process by using isoforms of G1 proteins encoded by a DNA.

The special technical feature of Group III is considered to be a method for modulating a certain characteristic of a cell or a process by using antibodies.

The special technical feature of Group IV is considered to be a method for treating tumor cells or HIV-infected cells or other diseased cells by using a recombinant animal virus vectors carrying a sequence encoding a surface protein and a sequence encoding a protein for the G1 protein.

The special technical feature of Group V is considered to be a method for modulating a certain characteristic of a cell or a cell process with inhibitors of one or more G1 proteins.

The special technical feature of Group VI is considered to be an anti-sense method for modulating a certain characteristic of a cell or a cell process.

The special technical feature of Group VII is considered to be a method for modulating a certain characteristic of a cell or a process by using a ribozyme procedure.

The special technical feature of Group VIII is considered to be a method for isolating and identifying proteins comprising the two-yeast hybrid system.

The special technical feature of Group IX is considered to be a method for screening of a ligand capable of binding to a protein comprising contacting an affinity chromatography matrix.

The special technical feature of Group X is considered to be a method for isolating and identifying DNA sequences comprising the two-yeast hybrid system.

The special technical feature of Group XI is considered to be a method for identifying and producing a ligand comprising screening, identifying and characterizing and producing said ligand.

Accordingly Groups I-XI are not so linked by the same or a corresponding special technical feature as to form a single general inventive concept.

The inventions listed as Groups I-XI do not relate to a single inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the reasons set forth above.

Should Group I, Group II or Group XI be elected, restriction is further required under 35 USC 372.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single inventive concept under PCT rule 13.1.

The species are as follows:

(a) Distinct members of compounds or substances listed as a DNA sequence encoding a G1 protein in Figure 1 or Figure 2.

(b) Distinct members of compounds listed as a protein of G1 in Figure 1 or Figure 2.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The claims are deemed to correspond to the species listed above in the following manner:

Claims 3 and 4, and claims dependent therefrom correspond to the species of (a).

Claims 12, 13, 40, and 41, and claims dependent therefrom correspond to the species of (b).

The following claim(s) are generic, claims 1, 11, and 41.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the species of (a) DNA sequence encoding G1 proteins and species of (b) isoform of a G1 protein; are different structurally and/or functionally with regard to their site of action, and the PCR Rules for Lack of Unity do not apply.

As the technical feature linking the members of the listed in claim does not constitute a special feature as defined by PCT Rule 13.2, particularly since the compound(s) and/or substance(s) listed in the claims do not share a structural feature in common with respect to their site of action. Thus, the requirement of unity of the invention is not fulfilled.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their divergent subject matter, restriction for examination purposes as indicates is proper.

Thus it would be unduly burdensome for the examiner to search all of the claimed inventions being sought in the pending claims.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ms. Tracey Johnson whose telephone number is (703) 305-2982.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian Whiteman whose telephone number is (703) 305-0775. The examiner can normally be reached on M-F, (730-400 EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Clark can be reached at (703) 305-4051.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center number is (703) 305-7401.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.

DAVE T. NGUYEN
PRIMARY EXAMINER

Brian Whiteman

Patent Examiner

May 11, 2001